

Electronic Certificate				
Document Number:	SA-UPAD-210010			
Document Name:	* Upadacitinib aRM Tool - Patient Alert Card - English Version 2.0 - June 2021			

Certification Statement

I hereby certify that I have examined the material referred to above and confirm that:

- 1. The piece has been approved according to the relevant Code, SOPs and Regulations
- 2. The information in the piece is balanced, accurate and a truthful presentation of the facts
- 3. When applicable, the content is consistent with the local Health Authority labeling document(s)
- 4. If applicable, the electronic version of the attached artwork is suitable for release to the market

Role	Signature				
Medical Certification	Yasser Nour Medical Director 17-Nov-2021 11:10:08 GMT+0000				

Show this card to any healthcare professional involved in your medical care – for example, your dentist or an emergency doctor.

This medicinal product is subject to additional monitoring. You can help by contacting the below mentioned address to report any side effects.

• For Extra copies please contact AbbVie Biopharmaceuticals GmbH 00966 55 828 2010

To report any side effects for Rinvoq please contact AbbVie Biopharmaceuticals GmbH - Hot Line: 00966 55 828 2010

Mailbox: MEAPV@abbvie.com

National Pharamacovioilance Center Saudi Food and

National Pharamacovigilance Center Saudi Food and Drug Authority - Fax: +966 11 205 7662 - SFDA Unified Call Center: 19999 E-mail: npc.drug@sfda.gov.sa | Website: https://ade.sfda.gov.sa/ Your name:

Consultant's name – who prescribed RINVOQ®:

Consultant's phone number:

The date you started RINVOQ®:

Version 2.0. Date approved June, 2021. https://ade.sfda.gov.sa/ Patient Alert Card
Keep this card with you all the time
This document has been reviewed and approved

by The Saudi Food and Drug Authority (SFDA).

Safety Information about RINVOQ® ▼ (upadacitinib) for patients

- This card contains important safety information you should be aware of – before and during treatment with RINVOQ®.
- Read the patient information leaflet for more information.

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RINVOQ® may make an existing infection worse or

increase the chance of you getting a new infection – for example tuberculosis (TB), shingles or viral hepatitis.

infection, such as: · Fever, sweating, chills, weight loss, or a cough that

Tell your doctor straight away if you notice signs of

- won't go away these may be signs of TB. Painful skin rash with blisters – this may be a sign of
- shingles.
- Feeling tired or short of breath this may be a sign of pneumonia.

Vaccines – used to help prevent infections Live vaccines (for example influenza vaccine by nasal

spray, varicella, measles/mumps/rubella) should not be given during RINVOQ® treatment, or just before starting RINVOQ® treatment. Before being given any vaccines, talk to your doctor –

Cholesterol

start a medicine to lower your cholesterol levels.

they will know which vaccines you should **not** be given

before or during treatment with RINVOQ®.

Your doctor will check your cholesterol levels while you

are taking RINVOQ® – this is to decide if you need to

pregnant, or if you become pregnant.

about effective contraception.

Contraception, pregnancy, and breast-feeding

• Use effective contraception while taking RINVOQ® -

• Tell your doctor straight away if you wish to become

and for 4 weeks after your last dose. Talk to your doctor

RINVOQ® must not be taken during pregnancy.

Blood clots in veins (DVT) or lungs (PE)

Do not breast-feed while using RINVOQ®.

Tell your doctor straight away if you get signs of DVT or PE, such as a painful swollen leg or chest pain.